DEPARTMENT OF THE ARMY
HEADQUARTERS, WALTER REED ARMY MEDICAL CENTER
6900 GEORGIA AVENUE NW
WASHINGTON, DC 20307-5001

WRAMC Regulation
No. 40-36 1 July 2002

Medical Services

ADVERSE DRUG REACTION REPORTING SYSTEM

1. **PURPOSE.** To provide ongoing surveillance of adverse drug reactions at this medical center in compliance with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Food and Drug Administration (FDA). To provide a procedure for reporting adverse drug reactions sustained by inpatients or outpatients treated at this medical center to the FDA, and for the documentation of adverse drug reactions in patient health records.

2. **APPLICABILITY.** This regulation is applicable to all organizational elements of Walter Reed Army Medical Center (WRAMC) to include outlying clinics.

3. **REFERENCES.**

a. AR 40-3, Medical, Dental, and Veterinary Care, 28 JAN 02.

b. AR 40-66, Medical Record Administration and Health Care Documentation, 03 MAY 99

c. American Society of Health-System Pharmacists “ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting,” BEST PRACTICES FOR HEALTH-SYSTEM PHARMACY 1998-1999.

d. Food and Drug Administration (FDA) Medwatch Form 3500.

e. FDA Vaccine Adverse Event Reporting System (VAERS) form.

4. **DEFINITION.**

a. Adverse Drug Reaction (ADR). An undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both.

(1) Discontinuation of the drug or reduction in drug dose (except for small reductions to increase tolerance).

(2) Results in hospitalization, prolongation of hospitalization or transfer to the intensive care unit.

(3) Requires supportive therapy (e.g., treatment with a prescription drug, mechanical ventilation).

(4) Results in temporary or permanent disability (e.g., renal failure, ototoxicity).

(5) Results in death of the patient.

*This regulation supersedes WRAMC Reg 40-36, dated 1 August 1999.

b. Side Effects. Some ADR's are expected side effects of therapy and are accepted because the benefits outweigh the risks. These side effects usually require little or no change in therapy. Examples include alopecia associated with chemotherapy or dry mouth associated with the use of antihistamines. These side effects should not be reported.

c. **Exception**: **Anthrax and Other Vaccine-Related Adverse Events**. Any adverse event (reporting of non-serious, local reactions is not necessary) coincident with the administration of anthrax or other vaccines, whether serious, non-serious, expected, or unexpected should be reported through the adverse drug reaction reporting system described in this regulation.

d. Medication errors. Do not confuse ADRs with medication errors, which are defined in WRAMC Regulation 40-68.

5. **RESPONSIBILITIES.**

a. All licensed health care providers are required to report ADRs when they are detected.

b. Department of Pharmacy (Pharmacy) will:

(1) Collect, analyze, and summarize reported ADRs, and provide ADR summaries to the WRAMC Medication Evaluation Subcommittee (MES) on a monthly basis.

(2) Report significant ADRs to the Food and Drug Administration as directed by the Pharmacy and Therapeutics Committee (PTC).

(3) Enter ADR information into the Composite Health Care System (CHCS) database.

(4) Provide a copy of the VAERS-1 report on all anthrax vaccine adverse reactions to the Army Medical Surveillance Activity (AMSA) and to the WRAMC Preventive Medicine Service.

c. MES will:

(1) Evaluate ADRs and forward significant ADRs to the PTC.

(2) Direct the CHCS documentation of significant ADRs.

d. PTC will direct the reporting of ADRs to the FDA.

6. **POLICIES.**

a. When an adverse drug reaction occurs in an inpatient, the practitioner who ordered the drug will be notified and entries will be noted in the "progress notes" and "nursing notes" of the patient's health record in the Clinical Information System (CIS).

b. When an ADR occurs in an outpatient, the health care professional aware of the reaction will notify the practitioner who ordered the drug, who in turn will ensure an entry is made in the patient's Outpatient Treatment Record.

c. For either inpatient or outpatient ADRs, the health care professional having knowledge of the adverse drug reaction will contact the Pharmacy to initiate the report.

d. After receiving a report, the Pharmacy will be responsible for ensuring complete data collection and analysis, and directing the ADR information to the appropriate people, WRAMC Committees, and outside organizations as described in paragraph 7.

7. **PROCEDURES.**

a. For all ADRs EXCEPT those associated with the anthrax vaccine.

(1) Any health care provider may report ADRs. Reporting can be accomplished by electronic mail via CHCS to the "g.wr drug rxn" mailgroup or by telephone to the Inpatient Pharmacy at 202-782-6221. The report should contain the patient's name, Social Security Number, medication history, a description of the suspected ADR, the temporal sequence of events, any remedial treatment required, and sequaelae. To assist health care providers in completing ADR reports, the CHCS Bulletin Board System, under the subtopic of Pharmacy, contains templates indicating information required to report ADRs for both medications (DRUGRXN) and vaccines (VAXRXN).

(2) The Pharmacy will make severity and probability assessment of ADRs, identify trends, and forward these comments with the ADR to the MES for review and evaluation.

(3) The MES will forward an ADR summary report monthly to the PTC for review and action. Serious or unexpected ADRs will be forwarded to the FDA using the Medwatch System (Medwatch Form 3500) or the VAERS.

(4) When negative trends are detected, the PTC will make recommendations on educational or administrative actions to reduce either the frequency or severity of an occurrence.

b. Anthrax vaccine ADRs.

(1) ADR reporting by health care providers should proceed as directed in 7.a. Information required for reporting can be found on the CHCS Bulletin Board System under the subtopic Pharmacy, VAXRXN. Health care providers are reminded that ALL adverse events coincident with the administration of anthrax vaccine whether serious, non-serious, expected, or unexpected must be reported.

(2) The Pharmacy, upon receipt of a reported adverse event to anthrax vaccine, will:

(a) File an official report through the VAERS-1 reporting system. VAERS phone number is 1-800-822-7967, fax number is 301-588-3491, and email is www.vaers.org.

(b) Fax a copy of the VAERS-1 report, after writing the patient's full Social Security Number on the form, to the Reportable Events Project Officer, Army Medical Surveillance Activity (AMSA) (fax: 202-782-0612) and the WRAMC Preventive Medicine Service (fax: 202-782-0308).

(c) Forward the health care provider generated CHCS E-mail message to the g.wr anthrax rxn mail-group.

(d) Incorporate the anthrax vaccine adverse event reports into the ADR summary described under paragraph 5.b.(1).

(3) The MES will incorporate the anthrax vaccine adverse event reports into the monthly ADR report to the PTC.

(4) The PTC will function as described in 7.a.(4).

8. **Documentation.**

a. Documentation of an ADR in an outpatient or inpatient medical record for issuance of a medical warning tag, will be done in accordance with AR 40-15.

b. A description of each suspected ADR and the outcome from the event should be documented in the patient's medical record. The Pharmacy will annotate all ADRs in the CHCS patient database.

The proponent agency of this publication is the Department of Pharmacy. Users are invited to submit comments and suggested improvements on a DA Form 2028 (Recommended Changes to Publications and Blank Forms) to the Commander, Walter Reed Army Medical Center, ATTN: MCHL-RX, 6900 Georgia Ave. NW, Washington, D.C. 20307-5001.

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